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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,964	11/08/2000	Philip A. Beachy	JHUC-P04-010	3944

28120 7590 04/22/2004  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/708,964	BEACHY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,15-17,20,22,23,27,28 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,15-17,20,22,23,27,28 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**Final Office Action on the Merits of a RCE**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1, 15-17, 20, 22, 23, 27, 28 and 36-39 are pending in the present application. The instant claims will be examined to the extent they read on the elected species.

***Double Patenting***

3. The rejection of claims 1, 15-17, 20, 23, 27, 28 and 36-39 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970 is maintained.

It is noted that applicant indicated a terminal disclaimer was filed with the response of February 2, 2004. Said terminal disclaimer is not of record in the present application.

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1, 15-17, 20, 22, 23, 27, 28, 36 and 37 under 35 USC, first paragraph, scope of enablement is maintained.

Applicant argues that the specification provides a link between the claimed invention and the molecules encompassed by the instant claims by a combination of structural descriptions, i.e., molecular weight of less than 750 amu, and functional descriptions based on how the compounds falling in the present claims behave.

Applicant also argues that the quantity of experimentation needed to make or use the instantly claimed invention is commensurate with the content of the specification.

Applicant's argument was considered but not persuasive for the following reasons.

According to applicant, the MPEP in its discussion of the requirements of 35 USC 112, 1<sup>st</sup> paragraph states that "one must define a compound by 'whatever characteristics sufficiently distinguish it'". However, the same section of the MPEP, i.e., 2163, states that the written description requirement is "separate and distinct from the enablement requirement". Thus, said section of the MPEP is not applicable to the rejection of record since the rejection is not one of description but of scope of enablement of the claimed invention.

According to MPEP § 2164.08, which discusses the scope of enablement, the focus of a scope inquiry is whether everything within the scope of the claim is enabled. Applicant's attention is directed to MPEP § 2164.08(a) that discusses a single mean claim. The instant claims are single means claims because they cover every conceivable organic molecule having a molecular weight less than 750 amu which interacts with smoothened and lessens the severity of a hedgehog gain-of-function, patched loss-of-function or smoothened gain-of-function phenotype while the specification discloses at most only those known to applicant. 35 USC 112, first

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paragraph requires the specification contain a description of the invention in full, clear, concise and exact terms as to enable the skilled artisan in the art to make and use the same. The present specification lacks description of the claimed invention in full, clear, concise and exact terms as to enable the skilled artisan in the art to make and use the claimed invention commensurate in scope with the instant claims. Because of the lack a reasonable correlation between the present specification and the broad scope of protection sought in the claims, it is the examiner's position that a rejection under 35 USC 112, first paragraph based on the scope of enablement of the claimed invention is proper.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 15-17, 20, 22, 23, 27, 28, 36 and 37 under 35 USC, first paragraph, scope of enablement is maintained.

**5. The rejection of claim 28 under 35 USC 112, second paragraph is withdrawn.**

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1, 20, 36, 38 and 39 under 35 USC 102(b) over Gerashchenko et al. is maintained.

Applicant argues that, unlike the present invention, the proliferation disclosed by the prior art refers to an aggregative kind wherein different types of phagocytes

congregate as part of an inflammatory response to injury. Applicant's argument was considered but not persuasive for the following reason.

Contrary to the argument presented by applicant, the present specification discloses a reduction in abnormal proliferation and differentiation of affected epithelium, which helps to reduce the severity of inflammatory events (see for example, page 57, line 27-page 58, line 27; page 62, lines 20-27). Like the present specification, the prior art encompasses the reduction in the proliferation of cells, such as epithelial cells, utilizing jevine.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 20, 36, 38 and 39 under 35 USC 102(b) over Gerashchenko et al. is maintained.

### ***Claim Rejections - 35 USC § 103***

**7. The rejection of claims 15-17, 22, 23, 27, 28 and 37 under 35 USC 103(a) over Gerashchenko et al. is maintained.**

Applicant's argument and the examiner's response are as discussed above in #6.

### ***Conclusion***

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Telephone Inquiry***

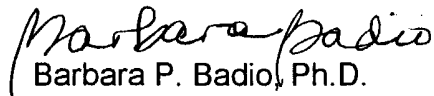
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB

April 21, 2004